



Primmed BV
De Huchtstraat 14
1327 EE Almere
Netherlands

Oslo, 17.12.2019

Your ref.:
[Your ref.]

Our ref. :
2015/6468

Contact person:
Marianne Stave Sekkenes

Acceptance of notification of administrative change - Care Plus Anti Insect DEET Spray 20 % - NO-2015-0105

We refer to your notification for an administrative change to the biocidal product authorisation for Care Plus Anti Insect DEET Spray 20 % - NO-2015-0105, R4BP3 Case number BC-JJ055295-35. The Norwegian Environment Agency hereby accepts the notification.

Background

According to Article 50 (2) in Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, changes to the conditions laid down in a biocidal product authorisation shall be accepted/approved by the Competent Authority. Changes to a product authorisation are further described in Regulation (EU) No 354/2013.

Regulation (EU) No 528/2012 and Regulation (EU) No 354/2013 are implemented in Norwegian law through the Norwegian Biocide Regulation of 18 April 2017 No. 480.

Decision

We hereby confirm that we accept the notification for an administrative change to Care Plus Anti Insect DEET Spray 20 %. The notification concerns addition of the trade name Metode mygg spray 20 DEET as referred to in Section 1 of Title 1 to the Annex to Regulation (EU) No 354/2013. No other changes than the above mentioned is accepted with this letter.

The revised Norwegian Summary of Product Characteristics (SPC) is uploaded to R4BP3.

Label

In cases where the changes concerned in this letter have any consequences for the content on, or the design of the label, you are kindly requested to submit an electronic copy of the revised label with the Norwegian authorisation number, NO-2015-0105 to biocides@miljodir.no within three months from the date of this letter.

Best regards
Norwegian Environment Agency

This document has been signed electronically

Marianne Stave Sekkenes
Senior Adviser